K033449

JAN - 7 2004

510(k) SUMMARY
(21 C.F.R. §§ 807.87(h), 807.92)

1. **Applicant Information/Address:**
Professional Dental Technologies Therapeutics, Inc.
500 White Dr.
Batesville, Arkansas 72501

2. **Contact Person/Telephone:**
Joann Underwood
870-698-3571 (Phone)
870-698-3570 (Fax)

3. **Date Summary was Prepared**
October 27, 2003

4. **Device's Name:**
   A. Proprietary Name:
   Pro-Dentec's Double-Pro™ Prophylaxis Paste with Fluoride Family of Devices

   B. Common Name:
   Dental Prophylaxis Paste

   C. Classification Name:
   Oral Cavity Abrasive Polishing Agent (21 § CFR 872.6030)

   D. Product Code:
   EJR

5. **Legally Marketed Predicate Device:**
NUPRO® Prophylaxis Paste with Fluoride made by Dentsply (K912945)

6. **Description of the Device**

The Double-Pro™ Prophylaxis Paste with Fluoride family of devices, manufactured by Professional Dental Technologies Therapeutics, Inc., are oral cavity abrasive polishing agents that contain fluoride, an abrasive (in one of several available levels of grit courseness), a sweetener, water, flavoring, color, thickeners, and preservatives. Double-Pro™ is intended for use by dental professionals, during professionally administered dental prophylaxis treatment (tooth-cleaning), to polish and clean calculus, stains, and other accretions from the teeth. Double Pro™ prophy paste is applied to patients' teeth with a prophy angle and rotating rubber cup. Use of Double-Pro™ Prophylaxis Paste with Fluoride family of devices is to be limited to individuals who are professional trained to perform dental prophylaxis.

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7. Statement of Intended Use

The Double-Pro™ Prophylaxis Paste with Fluoride family of devices, manufactured by Professional Dental Technologies Therapeutics, Inc., is intended to be used for cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment.

8. Summary Comparison Of Devices

Double-Pro™ Prophylaxis Paste with Fluoride family of devices are substantially equivalent to the predicate device, NUPRO® Prophylaxis Paste with Fluoride made by Dentsply (K912945). Both contain substantially similar ingredients, including abrasive material, flavor and coloring agents, and releasable fluoride, and are available in several different flavors and grits. Both are intended for use by dental professionals, during professionally administered dental prophylaxis treatment, to clean and polish teeth. Both products are applied directly to the teeth using a handpiece attachment.

Double-Pro™ Prophylaxis Paste with Fluoride family of devices has fluoride concentrations that are substantially equivalent to those of NUPRO®. The fluoride release rate for Double-Pro™ demonstrates the release of 1.23% fluoride (+/- 10%) – identical to the fluoride level of NUPRO®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2004

Mr. Joann Underwood
Attorney
Professional Dental Technologies Therapeutics, Incorporated
500 White Drive
Batesville, Arkansas 72501

Re: K033449
Trade/Device Name: Double-Pro™ Prophylaxis Paste with fluoride Family of Devices
Regulation Number: 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: I
Product Code: EJR
Dated: October 27, 2003
Received: October 29, 2003

Dear Mr. Underwood:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033449

510(k) Number (if known): _____

Device Name: Double-Pro™ Prophylaxis Paste with Fluoride
Family of Devices

Indications For Use: To be used for cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033449

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____